

UNITED STATES DISTRICT COURT  
DISTRICT OF MARYLAND

Chambers of  
**GEORGE L. RUSSELL, III**  
United States District Judge

101 West Lombard Street  
Baltimore, Maryland 21201  
410-962-4055

January 18, 2024

MEMORANDUM TO PARTIES RE: Jianyi Zhang v. US FDA  
Civil Action No. GLR-22-3126

Dear Parties:

Pending before the Court is Defendant US FDA's (the "FDA") Motion to Dismiss, or in the Alternative, for Summary Judgment, (ECF No. 12), self-represented Plaintiff Jianyi Zhang's Motion to Stay, (ECF No. 14), Motion to Lift Stay, (ECF No. 17), and Motion to Amend Petition, (ECF No. 19). The Motions are ripe for disposition, and no hearing is necessary. See Local Rule 105.6 (D.Md. 2023). For the reasons set forth below, the Court will grant the FDA's Motion, deny as moot Zhang's Motion to Stay and Motion to Lift Stay, and deny the Motion to Amend Petition.

**Background**

Zhang is a doctor who practiced in Virginia.<sup>1</sup> (See Compl. ¶ 3, ECF No. 1). He alleges that the FDA (referring to the United States Food and Drug Administration) suspected him of fraud and conspiracy to distribute controlled substances, including opioids. (See id. ¶¶ 5–6). On August 18, 2018, the FDA and the Virginia State Police Department executed a search warrant at Zhang's office. (Id. ¶ 5). They seized Zhang's medications, supplements, and herbal treatments and never returned them. (Id. ¶ 11). Following an investigation, the FDA closed the case on June 15, 2021. (Id. ¶ 9). In the case report, dated February 22, 2022, the FDA "could not provide findings to support the allegations." (Id.). Indeed, Zhang had not prescribed drugs like oxycodone, hydrocodone, or oxycontin for almost ten years prior to the search. (Id. ¶ 10). The raid and investigation caused damage to Zhang's reputation. (Id. ¶ 12). For example, local pharmacies refused to fill his prescriptions, resulting in loss of income and mental anguish. (Id.).

On May 22, 2022, Zhang sent Standard Form 95 (the "Form") to the FDA as required by the Federal Tort Claims Act ("FTCA"). When the FDA did not respond, he filed the instant case on December 2, 2022. (ECF No. 1). In the Complaint, Zhang makes the following claims: violation of the Fourth Amendment for unreasonable search (Count I); violation of the Fourteenth Amendment for treating Zhang differently based on his national origin (Count II); and violation of the Fifth Amendment for lack of due process (Count III). (Compl. ¶¶ 15–25). Zhang appears to bring these claims under either 42 U.S.C. § 1983 or the FTCA. (See id. ¶ 25). He seeks damages, including lost profits and emotional damages. (Id. ¶¶ 26–30).

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<sup>1</sup> Unless otherwise noted, the Court takes the following facts from the Complaint (ECF No. 1) and accepts them as true. See Erickson v. Pardus, 551 U.S. 89, 94 (2007).

The FDA filed the instant Motion to Dismiss, or in the Alternative, for Summary Judgment, on March 24, 2023. (ECF No. 12). On April 8, 2023, Zhang filed a Motion to Stay, in which he also made several arguments in opposition to the FDA's Motion to Dismiss. (ECF No. 14). The FDA opposed the Motion to Stay on April 21, 2023 (ECF No. 15), and Zhang filed a Reply on May 8, 2023, (ECF No. 16). Zhang subsequently filed an unopposed Motion to Lift Stay on November 15, 2023, (ECF No. 17), and a Motion to Amend Petition on December 13, 2023, (ECF No. 19). The FDA filed an Opposition to the Motion to Amend on December 19, 2023, (ECF No. 20), and Zhang filed a Reply on December 31, 2023, (ECF No. 21).

### **Conversion**

The FDA's dispositive motion is styled as a motion to dismiss under Federal Rule of Civil Procedure 12(b)(1) and (6) or, in the alternative, for summary judgment under Federal Rule of Civil Procedure 56. A motion styled in this manner implicates the court's discretion under Rule 12(d) of the Federal Rules of Civil Procedure. See Kensington Vol. Fire Dep't, Inc. v. Montgomery Cnty., 788 F.Supp.2d 431, 436–37 (D.Md. 2011), aff'd, 684 F.3d 462 (4th Cir. 2012). This Rule provides that when “matters outside the pleadings are presented to and not excluded by the court, the [Rule 12(b)(6)] motion must be treated as one for summary judgment under Rule 56.” Fed.R.Civ.P. 12(d). The Court “has ‘complete discretion to determine whether or not to accept the submission of any material beyond the pleadings that is offered in conjunction with a Rule 12(b)(6) motion and rely on it, thereby converting the motion, or to reject it or simply not consider it.’” Wells-Bey v. Kopp, No. ELH-12-2319, 2013 WL 1700927, at \*5 (D.Md. Apr. 16, 2013) (quoting 5C Wright & Miller, Federal Practice & Procedure § 1366, at 159 (3d ed. 2004, 2012 Supp.)).

Here, the FDA has filed an affidavit in support of its Motion, as well as documents related to the administrative exhaustion of Zhang's case, including the Form and emails between Zhang and federal officials concerning his FTCA claims. (ECF Nos. 12-2, 12-3, 12-4). The Court declines to convert the Motion into one for summary judgment, but it will consider the administrative record in its analysis of the Motion to Dismiss. Ordinarily, a court may not consider extrinsic evidence when resolving a Rule 12(b)(6) motion. See Chesapeake Bay Found., Inc. v. Severstal Sparrows Point, LLC, 794 F.Supp.2d 602, 611 (D.Md. 2011). But this general rule is subject to several exceptions, including documents attached to the motion to dismiss, so long as they are integral to the complaint and authentic, see Blankenship v. Manchin, 471 F.3d 523, 526 n.1 (4th Cir. 2006). A court may also consider documents referred to and relied upon in the complaint—“even if the documents are not attached as exhibits.” Fare Deals Ltd. v. World Choice Travel.com, Inc., 180 F.Supp.2d 678, 683 (D.Md. 2001); accord New Beckley Mining Corp. v. Int'l Union, United Mine Workers of Am., 18 F.3d 1161, 1164 (4th Cir. 1994). In the event that any of these properly considered extra-pleading materials conflict with the “bare allegations of the complaint,” the extra-pleading materials “prevail.” Fare Deals, 180 F.Supp.2d at 683; accord RaceRedi Motorsports, LLC v. Dart Mach., Ltd., 640 F.Supp.2d 660, 664 (D.Md. 2009).

Here, Zhang referred to the Form in his Complaint, and there is no dispute that documents relating to the administrative record are integral to his case and authentic. See White v. Mortg. Dynamics, Inc., 528 F.Supp.2d 576, 579 (D.Md. 2007) (finding that documents from the administrative record were integral to plaintiff's complaint). Accordingly, the Court will consider these documents in its analysis below.

## **Standard of Review**

Federal Rule of Civil Procedure 12(b)(1) requires a plaintiff to establish the Court's subject-matter jurisdiction by showing the existence of either a federal question under 28 U.S.C. § 1331 or diversity jurisdiction under 28 U.S.C. § 1332. A plaintiff may establish federal question jurisdiction by asserting a claim that arises from a federal statute or from the U.S. Constitution. Fed.R.Civ.P. 12(b)(1). To show that the claim arises on one of these bases, the federal question must appear “on the face of the plaintiff’s properly pleaded complaint.” AES Sparrows Point LNG, LLC v. Smith, 470 F.Supp.2d 586, 592 (D.Md. 2007) (quoting Caterpillar, Inc. v. Williams, 482 U.S. 386, 392 (1987)). However, when a party challenges subject-matter jurisdiction, the Court may consider “evidence outside the pleadings” to resolve the challenge. Richmond, Fredericksburg & Potomac R. Co. v. United States, 945 F.2d 765, 768 (4th Cir. 1991) (internal citation omitted).

A defendant challenging a complaint under Rule 12(b)(1) may advance a “facial challenge, asserting that the allegations in the complaint are insufficient to establish subject matter jurisdiction, or a factual challenge, asserting ‘that the jurisdictional allegations of the complaint [are] not true.’” Hasley v. Ward Mfg., LLC, No. RDB-13-1607, 2014 WL 3368050, at \*1 (D.Md. July 8, 2014) (alteration in original) (quoting Kerns v. United States, 585 F.3d 187, 192 (4th Cir. 2009)). Here, the FDA asserts that Zhang failed to exhaust his administrative remedies properly, which is a factual challenge.

With a factual challenge, the plaintiff bears the burden of proving the facts supporting subject-matter jurisdiction by a preponderance of the evidence. U.S. ex rel. Vuyyuru v. Jadhav, 555 F.3d 337, 347 (4th Cir. 2009). In determining whether the plaintiff has met this burden, the Court “is to regard the pleadings’ allegations as mere evidence on the issue, and may consider evidence outside the pleadings without converting the proceeding to one for summary judgment.” Richmond, Fredericksburg & Potomac R. Co., 945 F.2d at 768. Nevertheless, the Court applies “the standard applicable to a motion for summary judgment, under which the nonmoving party must set forth specific facts beyond the pleadings to show that a genuine issue of material fact exists.” Id. The movant “should prevail only if the material jurisdictional facts are not in dispute and the [movant] is entitled to prevail as a matter of law.” Id. Unlike under the summary judgment standard, however, the Court is permitted to decide disputed issues of fact, Kerns, 585 F.3d at 192, and weigh the evidence, Adams, 697 F.2d at 1219. If the Court establishes that it does not have subject-matter jurisdiction, it “must dismiss the complaint in its entirety.” Id.

The purpose of a Rule 12(b)(6) motion is to “test[] the sufficiency of a complaint,” not to “resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses.” King v. Rubenstein, 825 F.3d 206, 214 (4th Cir. 2016) (quoting Edwards v. City of Goldsboro, 178 F.3d 231, 243 (4th Cir. 1999)). A complaint fails to state a claim if it does not contain “a short and plain statement of the claim showing that the pleader is entitled to relief,” Fed.R.Civ.P. 8(a)(2), or does not “state a claim to relief that is plausible on its face,” Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). A claim is facially plausible “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” Id. “Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” Id. Though the plaintiff is not required to forecast evidence to prove the elements of the claim, the

complaint must allege sufficient facts to establish each element. Goss v. Bank of Am., N.A., 917 F.Supp.2d 445, 449 (D.Md. 2013) (quoting Walters v. McMahan, 684 F.3d 435, 439 (4th Cir. 2012)), aff'd, 546 F.App'x 165 (4th Cir. 2013).

In considering a Rule 12(b)(6) motion, a court must examine the complaint as a whole, accept the factual allegations in the complaint as true, and construe the factual allegations in the light most favorable to the plaintiff. See Albright v. Oliver, 510 U.S. 266, 268 (1994); Lambeth v. Bd. of Comm'rs of Davidson Cnty., 407 F.3d 266, 268 (4th Cir. 2005). Complaints drafted by self-represented plaintiffs are held to a less stringent standard than those drafted by attorneys, and courts must liberally construe these complaints. See Johnson v. Silver, 742 F.2d 823, 825 (4th Cir. 1984). But the court need not accept unsupported or conclusory factual allegations devoid of any reference to actual events, United Black Firefighters v. Hirst, 604 F.2d 844, 847 (4th Cir. 1979), or legal conclusions couched as factual allegations, Iqbal, 556 U.S. at 678 (quoting Twombly, 550 U.S. at 555).

### **Motion to Dismiss**

The FDA makes three main arguments in its Motions to Dismiss: (1) § 1983 and Bivens claims do not apply to federal agencies; (2) Zhang failed to exhaust his administrative remedies under the FTCA; and (3) the FTCA did not waive the United States' immunity to constitutional torts. (Mem. L Supp. Def.'s Mot. Dismiss ["Mot. Dismiss"] at 2–3, ECF No. 12-1). The Court will address each of these arguments in turn.

First, the FDA is correct that § 1983 applies only to "persons," not federal agencies. See § 1983 (creating a cause of action against persons, meaning state or local officials, who subject citizens to a deprivation of rights). Thus, to the extent that Zhang asserts claims under that statute, he has not named a proper defendant and those claims must be dismissed.<sup>2</sup>

Second, the Court turns to the FDA's arguments concerning the FTCA. The FDA argues that Zhang failed to exhaust his administrative remedies, and therefore that his claims are barred. (Mot. Dismiss at 12–14). "The FTCA permits actions for damages against the United States for injuries caused by the tortious conduct of United States agents or employees acting within the scope of their employment." Rempersad v. United States, No. GJH-18-2629, 2020 WL 2794558, at \*4 (D.Md. May 29, 2020) (citing Williams v. United States, 50 F.3d 299, 305 (4th Cir. 1995)).

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<sup>2</sup> The Court also notes that even if Zhang had brought his claims for violations of his constitutional rights as Bivens claims, the FDA would still be an improper defendant. In Bivens v. Six Unknown Named Agents of Federal Bureau of Narcotics, 403 U.S. 388 (1971), the Supreme Court recognized an implied cause of action against federal officers alleged to have violated a citizen's rights. Id. at 396–97. But this cause of action applies only to federal officers, not federal agencies. Thus, to the extent that Zhang's claims could be construed as Bivens claims, they must fail. See Diamond v. U.S. Bank, N.A., No. TDC-19-1458, 2020 WL 2319112, at \*5 (D.Md. May 11, 2020) ("[F]ederal agencies may not be sued for constitutional claims under Bivens."). Additionally, because the Court has determined that Zhang cannot bring Bivens claims, it need not address the FDA's argument that any Bivens claim for violation of the Fourth Amendment would be time-barred.

The FTCA provides that a tort action against the United States “shall not be instituted . . . unless the claimant shall have first presented the claim to the appropriate Federal agency and his claim shall have been finally denied by the agency in writing and sent by certified or registered mail.” 28 U.S.C. § 2675(a). “The failure of an agency to make final disposition of a claim within six months after it is filed shall, at the option of the claimant any time thereafter, be deemed a final denial of the claim” for the purposes of instituting a claim in federal court. Id.

“Plaintiffs must file tort claims against the United States in precise compliance with the FTCA’s terms.” Shipley v. U.S. Postal Serv., 266 F.Supp.2d 657, 661 (M.D.N.C. 2003). “A claim is presented ‘when a Federal agency receives from a claimant . . . an executed Standard Form 95 or other written notification of an incident, accompanied by a claim for money damages . . . .’” Johnson v. U.S., No. WDQ–14–0582, 2014 WL 6490238, at \*3 (D.Md. Nov. 18, 2014) (quoting 28 C.F.R. § 14.2(a)). If an administrative claim is not “presented in writing to the appropriate Federal agency within two years after such claim accrues,” it “shall be forever barred.” 28 U.S.C. § 2401(b).

In the instant case, Zhang filed Standard Form 95, but he failed to sign it. (See Standard Form 95 at 2, ECF No. 12-3). Zhang argues that he re-submitted a timely executed Form, but that he “lost the proof of it.”<sup>3</sup> (Mot. Stay at 3, ECF No. 14). The administrative record does not contain a signed Form, and Zhang, as the Plaintiff, bears the burden of proof to show that he exhausted his remedies and that the Court has jurisdiction over his case. Geroux v. United States, No. TJS-22-3107, 2023 WL 4867518, at \*2 (D.Md. July 27, 2023) (“The burden of proving subject matter jurisdiction is on the plaintiff, ‘the party asserting jurisdiction.’” (quoting Adams v. Bain, 697 F.2d 1213, 1219 (4th Cir. 1982))). Accordingly, because Zhang has not shown administrative exhaustion, his FTCA claims must be dismissed. Because the Court has found a failure to exhaust, it need not address the FDA’s third argument concerning whether Zhang’s FTCA claims must be dismissed due to sovereign immunity.

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<sup>3</sup> Acknowledging that he cannot produce a signed Form, Zhang re-filed a signed form and filed a Motion to Stay (ECF No. 14) to allow six months to accrue. After six months passed, Zhang moved to lift the stay, (ECF No. 17), and he also filed a Motion to Amend Petition, (ECF No. 19), in which he requests to amend his Complaint to include facts about his refile of the Form as well as unspecified “other changes” since he filed the original Complaint.

The Motion to Stay (ECF No. 14) and the Motion to Lift Stay (ECF No. 17) shall be denied as moot. The Court notes that Zhang’s efforts to refile his claim are improper. FTCA claims against a federal agency may be refiled, but only prior to the issuance of the agency’s final decision or, if the agency fails to make a final decision, the commencement of suit in the district court. 28 C.F.R. § 14.2(c); see also 5 C.F.R. § 177.102(e). Here, Zhang filed this suit prior to refile of a signed Form, so his belated attempt to exhaust his remedies is improper and cannot save his FTCA claims.

The Motion to Amend Petition (ECF No. 19) shall also be denied. Zhang has failed to comply with Local Rule 103(6)(c), which requires the movant to submit a clean copy of the proposed amended complaint, as well as a redlined copy. Further, in light of the Zhang’s inability to refile the Form as explained above, it appears that his proposed amendment would be futile. See U.S. ex rel. Wilson v. Kellogg Brown & Root, Inc., 525 F.3d 370, 376 (4th Cir. 2008) (“[A] district court may deny leave if amending the complaint would be futile.”).

**Conclusion**

For the foregoing reasons, the FDA's Motion to Dismiss, or in the Alternative, for Summary Judgment, (ECF No. 12), construed as a motion to dismiss, is GRANTED. Zhang's Motion to Stay, (ECF No. 14), and Motion to Lift Stay, (ECF No. 17), are DENIED AS MOOT. Zhang's Motion to Amend Petition (ECF No. 19) is DENIED. The Clerk is directed to CLOSE this case and MAIL a copy of this Order to Zhang. Despite the informal nature of this memorandum, it shall constitute an Order of the Court, and the Clerk is directed to docket it accordingly.

Very truly yours,

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/s/

George L. Russell, III  
United States District Judge